IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	James J. BARRY, et al.
SERIAL NO.	:	09/842,833
FILING DATE	:	April 27, 2001
FOR	:	METHOD AND SYSTEM FOR DELIVERY OF COATED IMPLANTS
EXAMINER	:	Alvin J. Stewart
GROUP ART UNIT	:	3774
CUSTOMER NO.	:	23838
CONFIRMATION NO.	:	8482

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

REPLACEMENT APPEAL BRIEF UNDER 37 CFR 41.37

Sir:

In response to the Notification of Non-Compliant Appeal Brief of July 3, 2008, for which a response is due by August 3, 2008, and in response to the Final Office Action of July 27, 2007, the Advisory Action of February 1, 2008, and the Notice of Panel Decision from Pre-Appeal Brief Review of April 2, 2008, the Applicants submit this Replacement Appeal Brief in the above-referenced application. A Notice of Appeal with the appropriate fee was previously filed January 28, 2008, thus no fee is believed to be due. The Office is hereby authorized to charge any fees necessary for consideration of this paper to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

REAL PARTY IN INTEREST

Boston Scientific Scimed Inc., the assignee of record, is the real party in interest for all issues related to this application. The assignment and a subsequent change of name are recorded at reel 011772, frame 0127 and at reel 018505, frame 0868, respectively.

RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings known to Appellants, Appellants' legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1, 3, 5-11 and 24-32 are currently pending and stand finally rejected. Claims 2, 4 and 15-23 were previously cancelled. Claims 12-14 are currently withdrawn from consideration as non-elected.

Claims 1, 3, 5-11 and 24-32 are subject to appeal.

STATUS OF AMENDMENTS

The amendment filed October 25, 2007, subsequent to the final rejection, to add a comma to claim 1 was not entered by the Examiner.

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a coated implant delivery system. Specifically, with reference to example embodiments within the scope of claim 1 described in the specification and illustrated in the figures, claim 1 is directed to a coated implant delivery system comprising:

- an implant delivery device with a first end, a second end, and an inner lumen (paragraph [0007], lines 3-4; Figure 6, implant delivery device 42; Figures 1-3, implant delivery device 14),
- the first end having a releasable implant retention region (paragraph [0036], line 2; Figure 6, implant retention region 40; Figures 1-3, implant retention region 13),
- the releasable implant retention region having an accessible surface (paragraph [0007], lines 5-6),
- the accessible surface of the releasable implant retention region having an implant adhesion-resistant treatment (paragraph [0007], lines 6-7; paragraph [0036], lines 3-6; Figures 4 and 6, implant adhesion resistant treatment 41);
- a releasable implant (paragraph [0037], lines 1-2; Figure 5, stent 51; Figures 1-3, coated support 11)
- having an implant coating (paragraph [0037], lines 2-3; Figure 5, stent coating 50; paragraph [0027], lines 7-8; Figs. 1-3, coating 10),
- the releasable implant releasably positioned in physical communication with the implant adhesion-resistant treatment on the accessible surface of said releasable implant retention region (paragraph [0027], line 4-7; Figures 1 and 2; paragraph [0038], lines 2-3),

- the implant coating facing the implant adhesion-resistant treatment on the releasable implant retention region (paragraph [0027], lines 7-8; Figures 1-3)
- wherein the implant adhesion-resistant treatment prevents the implant coating from being stripped from an implant surface (paragraph [0029], lines 3-9; paragraph [0038], lines 10-12).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1, 3, 7, 11 and 24-32 are unpatentable under 35 U.S.C. 103(a) as being obvious over US Patent 4,950,227 to Savin et al. ("Savin") in view of US Patent 6,287,285 to Michal et al. ("Michal").
2. Whether claims 5, 6 and 8-10 are unpatentable under 35 U.S.C. 103(a) as being obvious over US Patent 4,950,227 to Savin et al. ("Savin") in view of US Patent 6,287,285 to Michal et al. ("Michal") in further view of US Patent 5,902,631 to Wang et al. ("Wang").

ARGUMENT

1. Rejection Under 35 USC §103 Over US Patent 4,950,227 to Savin et al. in view of US Patent 6,287,285 to Michal et al.

Claims 1, 3, 7 and 11 and 24-32

Savin fails to disclose all the limitations of claim 1. Specifically, for example, Savin does not disclose an implant adhesion-resistant treatment on the accessible surface of the delivery device, and Savin does not disclose a releasable implant having an implant coating on the surface in contact with the accessible surface, wherein the implant adhesion-resistant treatment prevents the implant coating from being stripped from an implant surface.

Savin describes a stent delivery system comprising a balloon 14, a stent 16, and two sleeves 18, 20 for holding the stent on the balloon. Savin fails to disclose an adhesion resistant treatment on the outer surface of the balloon (accessible surface) that is in physical communication with the inner surface of the stent. In the Final Office Action, the Examiner refers to column 4, lines 55-57 for this limitation, however this passage merely states, "a lubricating solution can be provided between the balloon 14 and sleeve 18 and 20 to aid in release of stent 16 from the sleeves." As can be seen by comparing Figures 1 and 2 of Savin, when the balloon 14 is expanded, the sleeves 18, 20 slide relative to the balloon 14, allowing release of the ends of the stent 16. It can be seen from Figure 1 that a large extent of the sleeves 18 and 20 directly contact the balloon 14 at an area away from the stent 16. Savin specifically states that the "lubricating solution" can be provided "between the balloon 14 and sleeve 18 and 20." Savin does not disclose an adhesion resistant coating that is located between the **implant** and the delivery device, but rather provides that a "lubricating solution" may be located between

the balloon and the **sleeves**. The sleeves 18 and 20 are not part of the stent 16. Savin does not state that there is any coating between the stent and the balloon. Thus, Savin fails to disclose an "accessible surface of the releasable implant retention region having an implant adhesion-resistant treatment" with a "releasable implant releasably positioned in physical communication with the implant adhesion-resistant treatment," as claimed in claim 1.

Savin also does not disclose an implant coating on the inner surface of the stent that is in physical communication with the balloon. The Examiner admits that "Savin et al. does not disclose a stent having a first implant coating." (Final Office Action, Page 3). Although Savin states that the stent can have a lubricious coating (Savin, claim 17), there is no disclosure or teaching of what surface this coating would be on, i.e. whether the coating is on the inner surface or outer surface. Additionally, since it is known to put a lubricious coating on the **outer** surface to assist in reducing the friction during insertion into the body lumen (Michal, col 1, lines 17-21), one of ordinary skill in that art would understand that any lubricious coating on the stent in Savin would be on the *outer surface* of the stent. Thus, Savin fails to disclose an implant coating on the inner surface of the stent as recited in claim 1.

Furthermore, claim 1 recites that "the implant adhesion-resistant treatment prevents the implant coating from being stripped from an implant surface." Since Savin fails to describe any coating on the inner surface of a stent, there would be no motivation to provide an adhesion resistant coating on the delivery device to preserve a non-existent coating on the inner surface of the stent. There is no coating to be stripped from the inner surface. Thus, Savin does not disclose all the limitations of claim 1 (and all claims that depend therefrom).

Michal does not cure the deficiencies of Savin. Michal describes a therapeutic or lubricious coating for an intracorporeal medical device that allegedly strongly adheres to the

surface of the device. Michal gives two reasons for having a coating. First, Michal states that "intravascular devices, such as catheters and guidewires, are more easily maneuvered within a patient's vasculature when the **friction between the walls of the vessel and the intravascular device** is reduced," and that the "friction may be reduced by coating the device with a hydrophilic compound which becomes slippery after adsorbing an appreciable amount of water." (Michal, col. 1, lines 17-23 (emphasis added)). Second, Michal states that "various medical devices, such as stents or catheters, have been coated with therapeutic or diagnostic agents, to provide localized and possibly extended exposure **of the tissue** to the agent," adding that "drugs which prevent the proliferation of smooth muscle cells, or which promote the attachment of endothelial cells, can be coated on a stent which is then implanted at the site of a stenosis within **a patient's blood vessel**, to thereby inhibit restenosis following an angioplasty or stent implantation procedure." (Michal, col. 1, lines 52-60 (emphasis added)). Thus, in **both** reasons Michal gives for providing a coating, the purpose is to have the coating at the interface between the outermost portion of the device and **the patient's vessel wall**, e.g., the tissue of the blood vessel.

All of the Michal embodiments are consistent with this. For example, Michal describes and illustrates a first embodiment of a catheter 11 having a balloon 13 with a coating 18 on the outer surface (See Figure 1 and col. 6, lines 34-42). This embodiment has no stent on the balloon. Thus, the coating 18 interfaces directly with the patient's vessel wall. In a different embodiment, Michal describes and illustrates a stent on a catheter. In this embodiment, only the stent 30 is described and illustrated as having a coating 18 (See Figures 8 and 10-12 and col. 12, lines 8-23). In this case, it is entirely consistent with the two reasons Michal gives for having a coating that the coating be on the stent, because it is the stent that is at the interface with the

patient's blood vessel wall. Notably, when Michal discloses a stent and a catheter in combination, Michal specifically does not disclose a coating on both the stent and a coating on the catheter. Rather, Michal shows the coating only on the stent. It is the stent, not the balloon, that is at the interface with the vessel wall, and thus, consistent with the two reasons Michal gives for having a coating, it is only the stent, and not the balloon, that is coated. This further demonstrates that Michal is directed to a lubricious or therapeutic coating only on the outermost intracorporeal medical device (whether a stent or a catheter) where it contacts the vessel wall, for the two reasons Michal states.

With regard to Appellants' invention, Michal does not disclose an adhesion resistant treatment on the surface of a delivery device, such as a balloon, where that delivery device interfaces with an implant on the delivery device, with the implant also being coated. More specifically, Michal does not address the problem addressed by Appellants, which relates to the interaction between a coated implant and the delivery device. The Examiner proposes to combine the coated catheter of Michal with the coated stent of Michal even though Michal itself discloses that when a stent is combined with a catheter, only the stent should be coated to achieve the goals of Michal. The Examiner cannot simply pick and choose between embodiments of a reference and combine them where, as here, there is no reason provided in the prior art to do so. Furthermore, if Michal intended to have a coating on both the stent and the catheter, Michal would have shown this in the embodiment of Figure 8 and 10-12 or in some other embodiment, and presumably Michal would have articulated some reason for doing so. The lack of such a disclosure teaches away from Appellants' invention.

Although it may be known to use a lubricious coating on a catheter for ease of insertion into a body lumen, as described by Michal, there is no disclosure or teaching of a catheter having

an outer surface coated when this surface is covered by a stent. In fact, if a stent were placed on a catheter for insertion, a lubricious coating on the outer surface of the catheter for ease of insertion into the body lumen would be superfluous, since the catheter would be covered by the stent. Thus, the outer surface of the stent may have a lubricious or therapeutic coating, but there would be no motivation to also coat the outer surface of the catheter, since it would no longer be in contact with the body lumen, being covered by the stent.

In short, the embodiments of Michal disclose either a stent or a catheter having a coating, but nowhere are these two embodiments with coatings combined together, and there is no motivation for such a combination. As such, Michal does not disclose an implant coating on the inner surface of the stent that interfaces with the delivery device, and Michal does not disclose an adhesion resistant treatment on the outer surface of the delivery device that is in physical communication with the implant.

The Examiner states that the motivation for combining Michal and Savin is "in order to deliver therapeutic and pharmaceutical agents to a targeted area to inhibit or prevent restenosis." (Final Office Action, Page 3). Although this may provide motivation for providing a therapeutic on the **outer** surface of the stent that interfaces with the body lumen, this would still not provide motivation for providing an implant coating on the inner surface of the stent that interfaces with the delivery balloon. Additionally, neither Savin or Michal discloses the limitation of an adhesion resistant treatment on the outer surface of the delivery device that is in physical communication with the implant, as discussed above.

The Appellants' invention coats the area of the catheter that is in contact the stent in order to prevent stripping the stent coating when the stent is removed from the catheter and implanted in the body lumen. Such a problem was not even contemplated by Michal. Michal is directed to

a wholly distinct issue of creating a lubricious or therapeutic coating for interfacing with the patient's vessel wall, wherein the coating allegedly strongly adheres to the device. Thus, the combination of Michal and Savin does not disclose all of the limitations of claim 1 (and all claims that depend therefrom).

In the Final Office Action, the Examiner states that "nowhere in the prior art discloses that the implant adhesion-resistant treatment is capable of removing the implant coating from the implant surface" (Final Office Action, page 2). It is not understood what the Examiner means. The implant adhesion-resistant treatment of the present invention prevents the implant coating from being stripped from an implant surface, as recited in claim 1. The prior art does not disclose such an adhesion resistant treatment. Such a treatment is to prevent removal of the implant coating, so it is not understood why the Examiner is stating that the prior art does not say that it can remove the coating. The problem of stripping was not previously appreciated in the cited prior art, thus there was no need to provide such a treatment to prevent stripping. Just because the prior art does not say that the coating *was* stripped does not mean that it *was not* stripped.

The Examiner also states that "it is an inherent characteristic of coating implants of being stripped from the coating by the blood vessel fluid of the patients during a period of time in order to treat a specific region instead of being stripped off by an adhesion resistant treatment" (Final Office Action, page 2). It appears that the Examiner is mischaracterizing how the coating is stripped from the device. Once an implant is placed within a body lumen, such as a blood vessel, the therapeutic agent of certain coatings can slowly elute into the surrounding tissue. There is no "stripping" of the coating when it is placed in the body lumen. Claim 1 has nothing to do with this process of drug elution, but rather is concerned with the delivery process. When the implant

is delivered to the target site, the present invention according to claim 1 prevents the coating from being stripped from the implant. Previous delivery devices of the cited prior art did not provide any mechanism to prevent this stripping problem.

The Examiner further states that "it will not be efficient for a stent to be stripped of the coating by the implant resistant treatment" (Final Office Action, page 2). The Examiner is using hindsight reasoning to reconstruct the Applicants' own invention. The Applicants recognized this problem of stripping and thus developed an implant adhesion resistant treatment to solve this problem. Simply because the prior art does not provide an efficient method does not provide motivation for creating the Applicant's invention.

Regarding Savin, the Examiner states that "col. 4, lines 55-57 clearly disclose that the lubricating solution is between the balloon and the sleeve, therefore the lubricating solution is between the balloon and the stent (see Fig. 1)" (Office Action, page 2). This statement does not make sense. In Figure 1, the sleeves 18 and 20 each overlap the balloon 14 for a certain distance and then overlap the stent 16 for a distance D. Since the reference states that the lubricating solution is provided only between the balloon and the sleeves, there is no disclosure that there is lubricating solution between the sleeves 18 and 20 and stent 16 in the region D. The sleeves are not part of the stent. Furthermore, even if the lubricating solution continued along the entire inner surface of the sleeves, which it does not, this coating would only be between the outer surface of the stent 16 and sleeves 18, 20 and there would still be no coating between the inner surface of the stent 16 and the balloon 14. Thus, Savin does not disclose at least this limitation of claim 1.

2. Rejection Under 35 USC §103 Over US Patent 4,950,227 to Savin et al. in view of US Patent 6,287,285 to Michal et al. in further view of US Patent 5,902,631 to Wang et al.

Claims 5, 6 and 8-10

For the reasons discussed above, Michal and Savin do not render obvious the invention of claim 1, and all claims that depend therefrom, and Wang does not cure these deficiencies. Wang describes a balloon catheter that has a portion with a lubricity gradient. However, the catheter is lubricious in order to allow movement within the lumen of the body, not to allow for release of a removable implant placed on the outer surface. In fact, Wang does not disclose any such removable implant on the catheter, let alone an implant having a coating, wherein the adhesion resistant treatment prevents the coating from being stripped from the implant. Thus, the combination of Michal, Savin, and Wang fails to disclose all the limitations of claim 1, and all claims which depend therefrom.

CONCLUSION

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned directly at (202) 220-4200.

The Office is hereby authorized to charge the fee for any additional fees or credit any overpayment to Kenyon & Kenyon LLP's Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON LLP

Dated: July 31, 2008

/Jocelyn D. Ram/
Jocelyn D. Ram
Reg. No. 54,898

KENYON & KENYON LLP
1500 K Street, N.W. – Suite 700
Washington, D.C. 20005-1257
Tel: 202) 220-4200
Fax: 202) 220-4201

CLAIMS APPENDIX

1. A coated implant delivery system comprising:

an implant delivery device with a first end, a second end, and an inner lumen,

the first end having a releasable implant retention region,

the releasable implant retention region having an accessible surface,

the accessible surface of the releasable implant retention region having an implant adhesion-resistant treatment;

a releasable implant having an implant coating,

the releasable implant releasably positioned in physical communication with the implant adhesion-resistant treatment on the accessible surface of said releasable implant retention region,

the implant coating facing the implant adhesion-resistant treatment on the releasable implant retention region

wherein the implant adhesion-resistant treatment prevents the implant coating from being stripped from an implant surface.

3. The coated implant delivery system of claim 1 wherein the implant delivery device is a balloon catheter.

5. The coated implant delivery system of claim 1, wherein the implant adhesion-resistant treatment includes a therapeutic.

6. The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive silicone coating.

7. The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive hydrophilic coating.

8. The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive hydrogel coating.

9. The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive carbowax coating.

10. The coated implant delivery system of claim 1 wherein the implant adhesion-resistant treatment includes a non-adhesive PEO coating.

11. The coated implant delivery system of claim 1 wherein the releasable implant is a balloon-expanding stent.

24. The coated implant delivery system of claim 1, further comprising two coaxial sleeves positioned in physical communication with the releasable implant retention region.

25. The coated implant delivery system of claim 1, wherein the implant adhesion-resistant treatment reduces shear and normal friction between the releasable implant and the implant delivery device.

26. The coated implant delivery system of claim 1, wherein the releasable implant retention region has the adhesion resistant treatment on an outer surface, and the releasable implant has the implant coating on an inner surface.

27. The coated implant delivery system of claim 1, wherein the releasable implant retention region has the adhesion resistant treatment on an inner surface, and the releasable implant has the implant coating on an outer surface.

28. The coated implant delivery system of claim 26, wherein an outer surface of the releasable implant includes a therapeutic.

29. The coated implant delivery system of claim 1, wherein an inner surface of the releasable implant includes a therapeutic.

30. The coated implant delivery system of claim 27, wherein the implant coating on the outer surface of the releasable implant includes a therapeutic.

31. The coated implant delivery system of claim 28, wherein the implant coating is on the inner surface and the outer surface of the implant.

32. The coated implant delivery system of claim 26, wherein the implant coating is on the inner surface and the outer surface of the implant.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.